Remarks

Of the 9 original claims, claims 1 and 2 have been amended, claims 3-9 have been withdrawn from consideration, and claims 10-22 have been added. Please cancel withdrawn claims 3-9 without prejudice to underlying subject matter. Support for these amendments may be found in the original claims and throughout the specification, e.g., page 61, lines 3-6, and pages 237-251. No new matter is introduced by these amendments.

With this response, claims 1-2 and claims 10-22 are now pending. Applicants do not believe that any fees are due at this time; however, should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct the fees from Arnold & Porter Deposit Account No. 01-2510.

For the Examiner's convenience, a list of currently pending claims is attached at the end of this document.

I. Restriction Requirement

With respect to the prior restriction requirement, the Examiner acknowledges the election of group I, claims 1 and 2, with traverse. However, the Examiner rejects the grounds for traverse and makes the restriction requirement final. The Examiner also notes the election of 10 nucleic acid SEQ IDs. While Applicants disagree with the restriction and election requirements, to facilitate prosecution, Applicants have amended the claims in accordance with the election of specific nucleic acid sequences to be examined.

II. Rejection of Claim 2 under 35 U.S.C. §101

Claim 2 was rejected under 35 U.S.C. §101, because the claimed invention is allegedly not supported by either a specific and/or substantial utility or a well established utility as outlined in the Revised Interim Utility Guidelines Training Materials ("Interim Guidelines").

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including "probes for assisting in the isolation of full-length cDNAs or genes ... used to make protein and ... to make the corresponding antibodies, gene mapping, isolation of homologous sequences, detection of gene expression as in Northern blot analysis, molecular weight markers, chromosomal markers, and for numerous other[s]." Office Action dated November 21, 2000, at page 5. The Examiner further recognizes that "protein may be used for detection of expression, antibody production, Western blots, etc." Office Action dated November 21, 2000, at page 5. However, the Examiner contends that none of these utilities constitutes a "substantial" or "specific" utility as defined in the "Interim Guidelines."

Applicants traverse this rejection. The Examiner's application of these "Interim Guidelines" ignores the presently disclosed utilities and contravenes well-established doctrines of utility developed in the courts.

It is well-established law that "when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 598 (Fed. Cir. 1983). As acknowledged by the Examiner, the specification describes multiple objectives and utilities that are met by the present invention. For example, the nucleic acid sequences recited in claim 2 are useful for obtaining other nucleic acid molecules from the same species, obtaining nucleic acid homologues, obtaining promoter sequence(s) and other genetic elements, determining

presence and/or identity of polymorphism(s), measuring level of mRNA in a sample, acting as marker nucleic acids or probes, *etc.* (*see e.g.,* Specification, beginning at page 81, under heading "Uses of the Agents of the Invention").

Many of these uses are directly analogous to the use of a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell, or organism. Significantly, the utility of a microscope under 35 U.S.C. §101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize nucleic acid molecules within a sample, cell, or organism. Such utility is indistinguishable from the legally sufficient utility of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. §101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather, the Examiner attempts to undermine the existing utilities by stating that the " ...the disclosed use(s) of these compositions are not specific and is(are) generally applicable to any nucleic acid and/or protein." Office Action dated November 21, 2000, at page 5. The Examiner further contends that, "[t]hese are non-specific uses that are applicable to nucleic acid(s) and/or proteins in general and not particular or specific to the nucleic acid(s) and/or protein(s) being claimed." Office Action dated November 21, 2000, at page 5.

In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law - there is no requirement of exclusive utility in the patent law. *See Carl Zeiss*

Stiftung v. Renishaw PLC, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) ("An invention need not be the best or the only way to accomplish a certain result…").

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading "into the patent laws limitations and conditions which the legislature has not expressed," a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 206 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 162 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

Applicants note that the claimed nucleic acid molecules encompass many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and isolate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a ***unique*** subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit the ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. §101.

Surprisingly, the Examiner contends that the credibility of the presently asserted utilities has not been assessed. Office Action dated November 21, 2000, at page 6.

Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined "by reference to, and a factual analysis of, the disclosure of the application." *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 753 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner "has the initial burden of challenging a presumptively correct assertion of utility in the disclosure." *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner "must do more than merely question operability – [he] must set forth factual reasons which would lead one skilled in the art to question the objective truth of the statement of operability." *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided…").

Here, the Examiner has not even attempted to meet this burden. Thus, the Examiner's admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific, and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claim 2 under 35 U.S.C. §101 is incorrect and should be withdrawn.

III. Rejection of Claim 2 under 35 U.S.C. §112, 1st Paragraph: Enablement

Claim 2 was rejected under 35 U.S.C. § 112, first paragraph, as not being enabled by the specification, because the claimed invention allegedly lacks utility (*i.e.* an invention with no utility cannot be enabled). This rejection has been overcome by the foregoing arguments regarding utility.

Moreover, the Examiner has not met the evidentiary burden required to impose an enablement rejection. A specification that discloses how to use the claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original). It is also well-established law that "the enablement requirement is met if the description enables any mode of making and using the invention." *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1361, 47 U.S.P.Q.2d 1705, 1719 (Fed. Cir. 1998) (emphasis added), *quoting Engel Indús. v. Lockformer Co.*, 946 F.2d 1528, 1533, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991).

As discussed above, the present specification discloses how to use the claimed nucleic acid molecules (*e.g.*, obtaining other nucleic acid molecules from the same species, obtaining nucleic acid homologues, obtaining promoter sequence(s) and other genetic elements, determining presence and/or identity of polymorphism(s), measuring level of mRNA in a sample, acting as marker nucleic acids or probes *etc.)*. The Examiner, however, has provided neither evidence supporting the rejection, nor any explanation of why the specification allegedly fails to enable such uses. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

Thus, the enablement rejection under 35 U.S.C. § 112, first paragraph, is incorrect and should be withdrawn.

IV. Rejection of Claims 1 and 2 under 35 U.S.C. §112, 1st Paragraph: Written Description

Claims 1-2 were also rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in a manner that reasonably conveys to one of ordinary skill in the art that the inventors had possession of the claimed invention at the time of filing. According to the Examiner, the specification provides insufficient written description to support the invention claimed. Applicants respectfully disagree.

As the Examiner notes, the purpose of the written description requirement is to ensure that the inventors had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). Although the Examiner acknowledges that the "Applicant was in possession of the isolated nucleic acid sequences represented by the claimed SEQ ID NOs at the time of invention," the Examiner alleges that the "specification provides insufficient written description to support the invention claimed." Office Action dated November 21, 2000 at page 8.

In fact, Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence of SEQ ID NOs: 1, 100, 147, 153, 158, 161, 180, 184, 199 and 232. Furthermore, as Table A illustrates, the instant specification provides a functional characterization of each

disclosed sequence based on the enzyme encoded by each sequence. As is set forth in the specification, this functional characterization is based on homology of the claimed sequences to known coding sequences for enzymes of the tocopherol pathway. *See* Example 4, pages 235-236. Persons of ordinary skill in the art routinely characterize function based upon sequence homology.

Therefore, the specification does meet the burden imposed by *Vas-Cath Inc. v. Mahurkar*, 19 U.S.P.Q.2d 1111, because it "clearly allow[s] persons of ordinary skill in the art to recognize that [Applicants] invented what is claimed."

The Examiner alleges that the specification "does not describe any isolated nucleic acid sequences which encode the recited enzymes other than those already known in the prior art." Office Action dated November 21, 2000, at page 8. Applicants respectfully disagree. The specification describes a number of sequences encoding the recited enzymes, e.g., the claimed sequences. *See* Table A, column entitled Seq No. Furthermore, Table A describes sequences known to encode the recited enzymes. *See, e.g.,* Table A subheadings entitled deoxyarabiono-heptulosonate-P-synthase, putative deoxyarabiono-heptulosonate-P-synthase, and dehydroquinate synthase. The subheadings on the table categorize the sequences by the enzymes that they encode. Clearly, the specification does describe novel (e.g., the claimed sequences) and known (e.g., the sequences in Column entitled Seq No.) sequences that encode the recited enzymes. Accordingly, Applicants respectfully request that the rejection of claims 1 and 2 under 35 U.S.C. §112, 1st paragraph be withdrawn.

V. Rejection of Claim 2 under 35 U.S.C. §112, 1st Paragraph: Enablement

Claim 2 was rejected under 35 U.S.C. § 112, first paragraph, as, "containing subject matter which was not described in the specification in such a way as to enable one skilled in

the art …to make and/or use the invention." Office Action dated November 21, 2000 at page 9. The basis for this rejection is that "the specification does not provide support that the claimed sequences actually encode the enzymes recited in the claims." *Id.* This rejection has been overcome by the foregoing arguments regarding written description. With respect to the allegation that the specification does not teach "which claimed sequence encodes which enzyme" the Examiner's attention is respectfully directed to Table A and the subheadings which indicate to which enzyme a particular sequence corresponds.

Moreover, the Examiner has not met the evidentiary burden required to impose an enablement rejection. A specification that discloses how to use the claimed invention "must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995), *quoting In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original). As discussed above, the present specification discloses how to use the claimed nucleic acid molecules (e.g., obtaining other nucleic acid molecules from the same species, obtaining nucleic acid homologues, obtaining promoter sequence(s) and other genetic elements, determining presence and/or identity of polymorphism(s), measuring level of mRNA in a sample, acting as marker nucleic acids or probes *etc.)*. The Examiner has provided neither evidence supporting the rejection nor any explanation of why the specification allegedly fails to enable such uses. *See In re Wright*, 999 F.2d 1557, 1561-62, 27 U.S.P.Q.2d 1510,1513 (Fed. Cir. 1993); *Ex parte Lemak*, 210 U.S.P.Q. 306, 307 (Bd. App. 1981) ("pure conjecture" does not substantiate rejection for lack of enablement).

The Examiner has hypothesized that the functional characterization disclosed in the specification may not be accurate but has failed to provide any evidence supporting this

hypothesis. Office Action dated November 21, 2000 at page 11. The Examiner has failed to explain why a hypothesized misassignment of function would render the claimed invention inoperable or would prevent a person of ordinary skill in the art from using the claimed nucleic acid molecules. It is "always possible to theorize some combination of circumstances which would render a claimed composition...inoperative, but the art-skilled would assuredly not choose such a combination." *Ex Parte Cole*, 223 U.S.P.Q. 94, 95-96 (B.P.A.I. 1983). Unless and until the Examiner provides evidence that a person of ordinary skill in the art could not use the claimed nucleic acid molecules for the recited utilities, this rejection should be withdrawn. It is not the Applicants' burden to disprove every unsubstantiated hypothesis that can be imagined. Rather, it is the Examiner's burden to provide evidence in support of a rejection, not speculation.

Thus, the enablement rejection of Claim 2 under 35 U.S.C. §112, first paragraph, is incorrect and should be withdrawn.

VI. Rejection under 35 U.S.C. §102

Claim 1 was rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Lebrun (SPTREMBL seq-name: sp-plant: 024566) and Maxwell (WO 97/49816). A rejection under 35 U.S.C. 102(b) is proper if, *inter alia*, an anticipatory printed publication describes the invention more than one year prior to Applicants' effective filing date. With respect to §102(b), the Lebrun and Maxwell references cited by the Examiner appear to have been published after, or less than one year prior to, Applicants' filing date. Applicants presently claim a filing date of March 16, 1998. With regard to Lebrun, the sequence database entry was not even created until January 1, 1998. See line DT. Similarly, the international publication date of Maxwell is December 31, 1997. Each of these references is

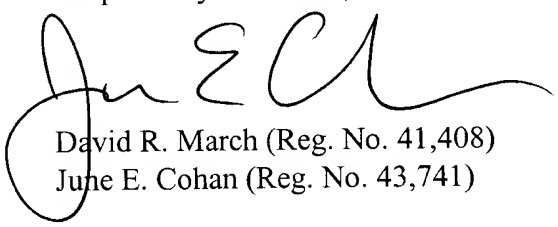
dated less than one year before the effective filing date of the present application. Therefore, these two references are not anticipatory to the presently claimed invention under §102(b).

Claim 1 was also rejected under 35 U.S.C. §102(b) and or §102(e) as allegedly being anticipated by Lebrun, Eichholtz (WO 92/06201), and Brown (U.S. 5,859,347). The Examiner contends that each of these three references anticipates claim 1. Applicants respectfully disagree. For a prior art reference to anticipate in terms of 35 U.S.C. §102, every element of the claimed invention must be identically shown in a single reference. *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 677, 7 U.S.P.Q.2d 1315, 1317 (Fed. Cir. 1988).

None of these three references teaches every element of the claimed invention because none of the references teaches a substantially purified nucleic acid molecule of the claimed invention. Lebrun and Eichholtz teach amino acid sequences, not nucleic acid sequences, and Brown teaches neither amino acid nor nucleic acid sequences. It is well-established law that a nucleic acid is not defined or described by its name (e.g., a cDNA encoding insulin), but "requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the DNA." *Regents of the University of California v. Eli Lilly* and Co., 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, (Fed. Cir. 1997). Therefore, none of Lebrun, Eichholtz, or Brown teaches all of the elements of the present claims. Accordingly, Applicants request that the rejection of claim 1 under 35 U.S.C. §102(b) and/or §102(e) be withdrawn.

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections and to pass the application to issue. The Examiner is invited to contact the undersigned at (202) 942-5071 with respect to any unresolved issues remaining in this application.

Respectfully submitted,



David R. March (Reg. No. 41,408)
June E. Cohan (Reg. No. 43,741)

Date: March 19, 2001

ARNOLD & PORTER
555 12th Street, N.W.
Washington, D.C. 20004
(202) 942-5000 telephone
(202) 942-5999 facsimile